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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,783	03/30/2004	Henrik S. Klint	8627-1901 (PA-5145-CON)	5211
48003 7590 03/10/2010 BRINKS HOFER GILSON & LIONE/CHICAGO/COOK PO BOX 10395 CHICAGO, IL 60610			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/813,783	Applicant(s) KLINT ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1, 4-10, 12-17, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al. (4,994,069) in view of Tekulve (5,797,953). Ritchart et al. disclose the invention substantially as claimed., at least in figures 7-8D and in col. 7, lines 22-33 and col. 8, line 20 to col. 9, line 21; a method for endovascular occlusion of a blood vessel area (70) or vessel lumen; where the method includes, inter alia, advancing a catheter (12) in a blood vessel; mechanically pushing a wire body (14) through the catheter, the wire body including a front end, a back end and a substantially straight section larger than a diameter of the blood vessel area; abutting a first wall portion of the blood vessel area (see fig. 8A), the wire body being substantially in a

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predetermined unloaded shape within the catheter; continuing to mechanically push the wire body out of a distal opening of the catheter, thereby by curving the section of the wire body toward a second wall portion of the blood vessel area (see fig. 8B), and frictionally locking the section to the first and second wall portions and column-loading the wire body between first and second wall portions due to mechanical pushing of the wire body (the blood vessel area is filled with the wire body), physically separating the wire body by pushing an entirety of the wire body of the wire body out of the distal opening of the catheter, occluding blood flow in the blood vessel area to be occluded using the frictionally-locked section of the wire body, where the blood flow is occluded after the wire body is physically separated from the catheter and after the catheter is removed, where the wire body has assumed a complexly curved shape as claimed; where the length of the section of the wire body is at least 20 mm, or at least 90 mm. (see col. 4, lines 63-64), where the wire body is made of thread extending helically around a center line of the wire body and absent of occlusion hairs, and where mechanically pushing the wire body comprises pushing on a guidewire (56) or stylet (16) that is unconnected to the wire body. However, Ritchart et al. do not specifically disclose the forming of a thrombus at a location of the wire body after the wire body is physically separated from the catheter and after the catheter is removed from the blood vessel area to be occluded, where the thrombus is formed around the wire body after its separation from the catheter. Tekulve teaches, at least in col. 4, lines 37-48; a wire body formed of a material that would promote thrombus formation when the wire body is at a blood vessel area to be occluded. It would have been obvious to one having

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ordinary skill in the art at the time the invention was made, in view of Tekulve, to modify the wire body and method of Ritchart et al., so that a thrombus is formed as claimed. Such modifications would promote thrombus formation at a blood vessel area and ensure complete occlusion of the blood vessel area.

Ritchart et al. also disclose a method for endovascular occlusion, where a complexly curved shape of the wire body is formed within a vessel without a change in temperature of the wire body; but they do not specifically disclose retracting the catheter between the abutting and continuing steps, that the wire body has a spring constant as claimed, and that the wire body is dimensioned as claimed. Nevertheless, Ritchart et al. also disclose, at least in col. 4, line 63 and col. 6, lines 39-48, that a long wire body may be applied at various hollow organ sites of different shapes and may be moved to at least expose a portion of the guidewire to blood (see fig. 8D). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to retract the catheter between the abutting and continuing steps. Such a step would allow a surgeon to reposition the catheter, so that the catheter can deliver a wire body and fill a vascular site, so that the catheter distal end does not interfere with the space-filling conformation of the wire body within the blood vessel area, and so that a portion of the guidewire may be exposed to blood for detachment of the wire body from the guidewire. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the wire body, so that it has a spring constant as claimed, since it has been held that where the general conditions of a claim

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are disclosed in the prior art, discovering the optimum or workable ranges (e.g., of a spring constant) involves only routine skill in the art.

Ritchart et al. also do not disclose that the front end of a wire body may be formed as a spiral with a decreasing helix diameter in the direction of the front end, where the front end is curved at least 120 deg. Tekulve teaches, at least in figure 3 and in col. 4, lines 5-26; a wire body that may be formed as a spiral with a decreasing helix diameter in the direction of the front end, where front end of the wire body is curved in a predetermined unloaded shape at least 120 deg. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Tekulve, to modify the front end of Ritchart et al. as claimed. Such a modification would allow further thrombus formation and further occlusion of a blood vessel area.

However, Ritchart et al. in view of Tekulve do not disclose dimensions of the largest helix diameter and wire body section as claimed. Nevertheless, it also would be a matter of obvious design choice to size the section and the rest of the wire body as claimed, since such modifications would have involved mere changes in the size of a component. A change in size is generally recognized as being within the skill of ordinary skill in the art.

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al. (4,994,069) in view of Tekulve (5,797,953), and further in view of Guglielmi et al. (5,122,136). Ritchart et al. in view of Tekulve disclose the invention substantially as claimed, but do not disclose that the blood vessel area is an aneurysm. Guglielmi et al. teach, at least in figures 4 and 5 and col. 8, lines 16-47; the insertion of a wire body into

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an aneurysm. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Guglielmi et al., to modify the method of Ritchart et al. in view of Tekulve, so that it is applied to an aneurysm. An aneurysm is a blood vessel area that can accommodate a wire body, and it is a location that is effectively treated with thrombus formation and occlusion induced by the insertion of a wire body.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al. (4,994,069) in view of Tekulve (5,797,953) and Guglielmi et al. (5,122,136), and further in view of Kupiecki et al. (5,669,931). Ritchart et al. in view of Tekulve and Guglielmi et al. disclose the invention substantially as claimed, but do not disclose that the front and back ends of the wire body are curved in the predetermined unloaded shape. Kupiecki et al. teach, at least in col. 4, line 62 to col. 5, line 5, that a wire body may have curves (i.e., helices) at the front end, along the entire length of the body, or spaced from the front end in a relaxed condition. Thus, it would have been a matter of obvious design choice, in view of Kupiecki et al., to curve the front end of the wire body of Ritchart et al. in view of Tekulve and Guglielmi et al. in an unloaded condition. Such a modification (i.e., helices) would enhance the occlusion of a vascular site to a desired degree with additional masses of wire body material concentrated at the ends of the wire body upon unloading of the wire body.

5. Claims 11 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al. (4,994,069) in view of Tekulve (5,797,953), and further in view of Kupiecki et al. (5,669,931). Ritchart et al. in view of Tekulve disclose the invention

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substantially as claimed, but do not disclose that the back end of the wire body is curved in the predetermined unloaded shape between 140 deg. and 340 deg., or that the front and the back ends are curved, and that the wire body is sized as claimed. Kupiecki et al. teach, at least in col. 4, line 62 to col. 5, line 5, that a wire body may have curves (i.e., helices) at the front end, along the entire length of the body, or spaced from the front end in a relaxed condition. Thus, it would have been a matter of obvious design choice, in view of Kupiecki et al., to curve the front and back ends of the wire body of Ritchart et al. in view of Tekulve (at least between 140 deg and 340) in an unloaded condition. Such modifications (i.e., helices) would enhance the occlusion of a vascular site to a desired degree with additional masses of wire body material concentrated at the ends of the wire body upon unloading of the wire body. Moreover, it would be a matter of obvious design choice to size the section and the rest of the wire body as claimed, since such modifications would have involved mere changes in the size of a component. A change in size is generally recognized as being within the skill of ordinary skill in the art.

Response to Arguments

6. Applicant's arguments filed on December 16, 2009 have been fully considered but they are not persuasive. Applicant concludes that Ritchart et al. does not disclose a wire body having a section that is substantially straight in a predetermined unloaded shape with a length that is larger than the diameter of the vessel or aneurysm where the section is substantially in the predetermined unloaded shape within the catheter. The Examiner respectfully disagrees. First, Applicant is reminded that claims are given their

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broadest reasonable interpretation. That is, Ritchart et al. disclose a section of the wire body that is within the catheter, where the section is "substantially straight." According to the Merriam-Webster Collegiate Dictionary, 10th edition, "substantial" is defined to be: "being largely but not wholly that is which is specified." Thus, the wire body of Ritchart et al., including minor undulations within the catheter, is largely but not wholly straight. Secondly, the wire body section is in a "substantially...predetermined...shape." The shape of the wire body section is largely predetermined in the sense that it is a wire formed into a coil-shape and straightened after being loaded within the catheter and prior to implantation in a patient's body. Finally, the wire body section is "substantially...unloaded" in the sense that, while the wire body is in the catheter, it is not pushed, moved, or column-loaded before it is implanted in the patient's body. The wire body section may be experiencing lateral forces from contact with the wall of the catheter lumen, but the wire body section is largely but not wholly (i.e., substantially) unloaded. Certainly, the wire body section is not column-loaded, where column-loading appears to be type of loading being considered in the claims. In short, Ritchart et al. indeed disclose a wire body having a section that is substantially straight in a predetermined unloaded shape with a length that is larger than the diameter of the vessel or aneurysm where the section is substantially in the predetermined unloaded shape within the catheter.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho, can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773